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M E M O R A N D U M

INTRODUCTION

This memorandum is written to provide a critical analysis of legal and scientific problems raised by Dr. L.C.F. Blackman's presentation as found in the Blue Book and in copies of slides used in oral presentations.

Legal Section

From a product liability standpoint, there are a number of problems with Dr. Blackman's position. These potential problems can be broken down into five basic categories: (1) admissions; (2) assurances of safety; (3) FDA jurisdiction; (4) duty to test; (5) cross-examination material.

A. Admissions

One of the most dangerous aspects of Dr. Blackman's presentation is the likelihood that some of his statements may be construed as admissions by BAT or, possibly, by others in the industry. These admissions arise in two contexts. First, by favorably citing expert opinion that low tar cigarettes are less hazardous than high tar cigarettes, Dr. Blackman may be admitting that cigarettes manufactured in the fifties and sixties did, in fact, pose a risk to health. Second, by stating that these experts believe that today cigarettes are "less" hazardous, Dr. Blackman may be admitting that present-day cigarettes are dangerous, although not as dangerous as earlier products. Despite Dr. Blackman's statement that he wants to make it clear that these are not industry positions, the selective use of medical

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opinion without providing sufficient attention to contrary views is perilously close to adoption.

The following may constitute a very dangerous admission:

> I have also tried to give some indication of the way the tobacco industry shares the concerns of those who are working in this area, and has tried to respond to those concerns (a) by undertaking and supporting research and (b) by introducing new products in line with medical and scientific opinions and with the changing demand of consumers. (p. 19 emphasis added).

It could be argued that by changing the design of a product in response to medical opinion, the manufacturer must have given great importance or value to the opinion.

B. Assurances of Safety

Many of the same statements which may be construed to be admissions that prior cigarettes were hazardous can also be considered to be assurances that present-day cigarettes are safe or safer--in other words, a dilution of the warning, thereby endangering the assumption of risk defense.

Closely related to the dilution of the warning issue is the use by Dr. Blackman of certain statements by the Surgeon General. If Dr. Blackman quotes or refers to the Surgeon General

in support of an argument that low tar cigarettes are safer, he must be very careful to include the Surgeon General's proviso that this may be true only if smoking patterns do not change. Otherwise, the industry might be accused of misleading the consumer regarding the Surgeon General's opinions. In effect, Dr. Blackman might be creating a duty to instruct the consumer regarding use of the product. Negligent failure to instruct is a basis for liability, as is negligent failure to warn.

C. FDA Jurisdiction

In recent years, certain anti-smoking organizations in this country have attempted to have the Food and Drug Administration assert jurisdiction over cigarettes, cigarette filters, or nicotine as drugs or devices under the Food, Drug and Cosmetic Act. The Food, Drug and Cosmetic Act defines a drug to be a substance which is, among other things, intended for use in the mitigation or prevention of disease. Similarly, a device is defined as an instrument, apparatus, etc., which, among other things, is intended for use in the mitigation or prevention of disease. As discussed in Appendix 1, courts in this country have held repeatedly that the question of "intent" is a question of the manufacturer's intent. Statements made by a manufacturer are extremely important in determining whether cigarettes, filters, or nicotine may be classified as drugs or devices. Thus, Dr.

Blackman's statements and his implications that filtered cigarettes are somehow safer than other cigarettes conceivably could mean that the manufacturer intends the filter or the filtered cigarette to aid in the prevention of disease. This could result in the Food and Drug Administration asserting jurisdiction over cigarettes. In that event, the FDA would have the power to regulate the sale, advertisement, of cigarettes, including designating them as a prescription drug and allowing their sale only on prescription by a doctor.

D. Duty to Test

According to Dr. Blackman, the industry has introduced new products as a result of medical and scientific opinion. His statement raises the issue of a manufacturer's duty to test its product and the product's components, such as additives. Attached as Appendix 2 is a confidential memorandum regarding a manufacturer's duty to test additives. By stating that the industry's marketing decisions have been made on the basis of scientific data, Dr. Blackman is giving the testing issue unwarranted prominence.

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E. Cross-Examination

In the event that a manufacturer other than BAT or Brown and Williamson were a party to a lawsuit, it is possible that the assurances of safety and admissions referred to above might not be admissible against that manufacturer as admissions. Nevertheless, the fact that a representative of one of the largest cigarette manufacturers in the world was making these statements, certainly could be used effectively in cross-examining industry witnesses. The fact that a representative of BAT was making assurances of safety, recognizing that past cigarettes were harmful, and stating that it is possible for a manufacturer to prevent disease by developing cigarettes that can be used safely when smoked at the rate of 10 to 20 per day, would be very effective with a jury.

Conclusion

In conclusion, specific statements made by Dr. Blackman, as well as the general tenor of the talk, have very definite product liability implications. There are possible admissions, assurances of safety, and statements which could lead to Food and Drug Administration involvement in the United States. In addition, quoting with approval papers or authors which the industry may have to challenge at a later date should be avoided. In

particular, the epidemiological studies cited by Dr. Blackman have consistently shown that smokers have higher risks of disease than non-smokers. The trend toward lower tar and nicotine cigarettes should not be represented as a response by the industry to certain medical opinion.

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SCIENTIFIC SECTION

The topics to be discussed in this section are the scientific problems with Dr. Blackman's presentation in the Blue Book, a survey of the significant medical opinion not supportive of the concept of a less hazardous cigarette and additional scientific problems and questions not addressed by Dr. Blackman. The first subsection will be devoted to a discussion of the major weaknesses, uncertainties and inconsistencies in the evidence which Dr. Blackman says is relied upon by experts who believe that lower yield cigarettes are less hazardous. Secondly, the survey of significant medical opinion contrary to this concept is intended to point out the highly selective and possibly misleading presentation of evidence by Dr. Blackman. A brief discussion of difficult scientific questions that can be asked of the industry as a result of Dr. Blackman's position will conclude this section.

A. Scientific Problems With Dr. Blackman's Presentation

The following discussion is not intended to be all encompassing but will focus on some of the major problems.

1. Epidemiological Studies (page 4). Six epidemiological studies are referred to by Dr. Blackman and their findings are summarized in terms of claimed reductions in incidences of

smoking associated diseases. Dr. Blackman states that these studies in the views of some researchers provide evidence that the modern cigarette is associated with a lower risk to health.

All of these studies with the exception of Hammond (1976) dealt with comparisons between filter and plain cigarettes. The relevance of these comparisons to cigarettes with reduced "tar" and nicotine yields is not at all clear.

In regard to his own study, Hammond points out that it involved switchers from high "tar" and nicotine cigarettes to low "tar" and nicotine cigarettes. Switching raises the serious question of possible bias from self-selected samples. That is, those persons who switched from high "tar" and nicotine cigarettes may be fundamentally different from those people who continued to smoke the higher yield cigarettes. In addition, Hammond was cautious in the conclusions that he drew from the study; he said that switching from the high yield to the low yield cigarettes "somewhat reduced the serious risks" and "was at least a small step in the right direction."

Dr. Michael Russell, the English psychiatrist, challenged the claims, based on these studies, that the gradual decline in reported lung cancer rates is necessarily due to the switching to the lower yield cigarettes. He contends that the "tar" and nicotine intakes by smokers have remained largely unchanged despite their switching to lower yield cigarettes.

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An additional problem with these studies arises because of the view that many of the smoking related diseases cannot be detected clinically until 20 or 30 years after smoking has begun--the lag period. Thus, none of these studies nor any presently underway can be expected to provide definitive information about the claimed decreased risks of lower yield cigarettes. In this regard an editorial in the British Medical Journal, November 14, 1981, noted that such information "is unlikely in much under 30 years."

2. Histological Studies of Auerbach. Dr. Blackman (p. 5) gives great emphasis to the findings reported by Auerbach and colleagues in a study of tissue taken from the bronchial tubes of U.S. veterans. Dr. Blackman quotes the authors of this study as stating in 1979 that the ten-fold decrease in carcinoma-in-situ reported over time has "tremendous significance in the future of lung cancer in the U.S." It is important to note that this is a prediction about future disease trends based on observed cellular changes. In fact, when one of the authors, Lawrence Garfinkel, was asked at the 1979 Cold Spring Harbor conference to explain the cellular changes in terms of the reduction of risks for various diseases, he responded "Remember this is not death, this is cellular changes." When he was asked in a related question if carcinoma-in-situ (called pre-cancerous changes by Dr. Blackman) is of necessity pre-malignant in the bronchus, Mr.

Garfinkel replied, "We can't tell directly." Finally, Mr. Garfinkel noted that the veterans who died during the 1970's had three cases of invasive carcinoma while those who died in the earlier period had only one case. He admitted that he was unable to explain this "anomaly" in the data.

3. Reported Decreases in Lung Cancer Rates in the U.K. In his discussion of the graphs (p. 2) which indicate a decrease in the lung cancer incidence among certain age groups, Dr. Blackman appears to suggest that this might be explained by changes in cigarette design. He fails to mention earlier work by Gilliam, Springett, and others who examined lung cancer trends in the early Sixties. In regard to trends of lung cancer reported in studies from England and Wales, Springett noted, "It appears that the steady increase of carcinoma of the lung is not only coming to an end but coming to an end in this highly specialized manner of extinction in the cohort born in the early years of this century." In other words, the turn-down in rates which are now being realized had been predicted by respected scientists long before the wide spread use of lower yield cigarettes. The natural pattern of disease or susceptible cohort theories raise questions about Dr. Blackman's treatment of lung cancer rates.

4. Gori's Theory of Critical Values. Gori's theory that critical daily levels of certain smoke components will not raise the smoker's level of risk, in a statistical sense, above

that of a nonsmoker is given serious attention by Dr. Blackman. Although he notes that the critical level approach is not popular in the medical world, he fails to point out the many serious scientific flaws in Gori's work. Besides his reliance on epidemiological studies as the source of his data, Dr. Gori has been criticized by statisticians for using erroneous techniques that lead to "untenable conclusions" and by physicians for his failure to consider whether the complex manipulations necessary to lower the yields of the six substances deemed important by Gori might well change the biological activity of the smoke. In a critical letter, Dr. F. Homburger states unequivocally that only smoke inhalation studies could establish whether the carcinogenic effects of smoke have indeed been reduced as implied by Gori.

Dr. Blackman's emphasis on Gori's work leads to the natural question of whether he is suggesting moderation which is tied closely to the concept of a daily critical level.

B. Serious Scientific Disagreement with the Concept of a Less Hazardous Cigarette.

1. 1979 Cold Spring Harbor Conference. Dr. E. L. Wynder, who appears to favor the development of what he calls "less harmful smoking products," gave the opening address at this conference. He acknowledged the need for and urged that further research be done in this area. He noted that the risk of tobacco

related cancers for smokers of lower yield cigarettes has not been "adequately researched." In a call for further research, he asks the descriptive epidemiologist "to extend his activities to metabolic epidemiological investigations to understand more fully the patterns of smoking behaviors and the effects of various types of cigarettes on diseases." Dr. Wynder's concerns about the state of scientific knowledge in this area suggest that extreme caution be observed.

Even Dr. Gori, in his summary appraisal of this conference, stated that "uncertainty about the specific attribution of risk to individual smoke components may be greater than ever now . . . Hence, it has been difficult to provide a rationale for deliberate reductions of specific components of smoke, aside from the self-fulfilling claims that the reduction of one or the other component may lead to reduced risk." Thus, even the most well-known advocate of the less hazardous cigarette voices concern about the lack of scientific knowledge in this area.

2. Conference on Research Needs on Low Yield Cigarettes, June 1980. The deliberations of this conference formed the basis for many of the conclusions drawn in the 1981 Surgeon General's Report. Dr. William Castelli of the Framingham Heart Study stated that many of the studies on this subject have not followed their subjects long enough to provide clinical insight as to whether there is more or less disease in the future. In regard to low yield cigarettes, he suggested that we could be "looking

at a lower dose with the same poisons which take a longer time to do their dirty work." M. R. Guenin of the Oak Ridge National Laboratory stated that considerable evidence exists that many smokers "compensate" for lower smoke delivery by altering their smoking characteristics. He then noted that it is unknown whether such practices might negate the claimed beneficial effect of smoking low delivery cigarettes. Dr. Henry C. McGill, University of Texas Health Science Center, stated that "without the knowledge of which components of cigarette smoke are responsible for augmenting cardiovascular disease, we are unable to suggest the design of low yield cigarettes which deliver low levels of these substances responsible for cardiovascular disease. Comments similar to these also apply to chronic obstructive pulmonary disease as well . . ."

3. The 1981 Surgeon General's Report. This report titled "The Changing Cigarette" addressed the question of whether these lower yield cigarettes carry decreased health risks to smokers. The general conclusion of the Surgeon General was that some cigarettes may be less hazardous than others and thereby may reduce the risks of smoking in a limited and selective fashion provided the smokers do not begin to smoke more or inhale more deeply. This summary recommendation is far from an endorsement of a concept of a less hazardous cigarette despite Dr. Blackman's slides. A more detailed examination of the conclusions of the

report reveals other serious reservations. The report frequently acknowledges the lack of comprehensive and conclusive evidence in this area. It notes that there is no epidemiological evidence to prove or disprove that there has been a decrease of cancers other than of the lung and larynx in smokers of lower "tar" and nicotine cigarettes. In regard to cardiovascular disease, the report concludes that the lower yield cigarettes appearing in the last 10 to 15 years have not produced a clearly demonstrated effect on these disease rates and that some studies suggest that the reported decreased risk of CHD may not have occurred at all. In regard to chronic obstructive lung disease, the report notes that whether there is a difference in risk for lower yield cigarette smokers is currently unknown. In regard to pregnancy and infant health, the report notes there is no evidence available that lower "tar" and nicotine cigarettes decrease or increase these health risks.

4. Other Research Opinions. Canadian researchers, Rickert, Robinson and Young, have reported that in some lower yield cigarettes the levels of certain constituents of the gas phase are actually increased. They write that "the possibility of an increase would be of little concern if the gas phase were inert or if anticipated levels of toxic compounds were inconsequential. Neither is the case." Thus, according to this study, some lower yield cigarettes may actually be more hazardous.

In The Daily Telegraph, June 6, 1981, Dr. Karl Fagerstroen is quoted as saying that weak cigarettes with low nicotine content may be a greater health hazard than strong cigarettes. He noted that the smokers of the lower yield cigarettes may smoke more and consequently inhale more carbon monoxide.

The 1981 annual report of the British-funded Medical Research Council stated that smokers do not cut their health risk significantly by switching to lower yield cigarettes. They claim that the smokers inhale as much "tar" and carbon monoxide as smokers of higher yield cigarettes.

Dr. Jerome Jaffe reported that low yield cigarette smokers smoke harder on these cigarettes, thus increasing the "tar" and nicotine yields significantly from that listed as a result of laboratory tests. Consequently, these lower yield cigarette smokers are exposed to roughly the same amounts of "tar" and nicotine as are present in the higher yield products.

C. Additional Problems and Questions.

By stating that the industry has responded to "that strong body of medical opinion" which holds that the lower yield cigarettes are less hazardous, Dr. Blackman is vulnerable to the question of why the industry did not respond to contrary medical opinion, or, equivalently, of how the industry selected the

medical opinion which it chose to follow. These troublesome questions remain even if the related issue of adoption by the industry of selected medical opinion can be successfully resolved. Several examples follow.

1. Other Diseases. Because little, if anything, is known about the effect of lower yield cigarettes on the risks of diseases associated with smoking (other than lung cancer, according to some researchers), it is entirely possible that these disease risks would be increased.

2. Initiation of Smoking. The medical community world-wide encourages people not to start smoking. In a paper by Silverstein, Felt and Kozlowski, it is reported that the availability of low nicotine cigarettes appears to make it easier for females to begin smoking.

3. Compensation. Dr. Blackman mentions that consumers should be made aware of the scientific opinion supportive of a less hazardous cigarette. If the industry points this out, it follows logically that it must also point out the great concern that switchers to lower yield cigarettes compensate by inhaling more or smoking more cigarettes. The question arises of whether this concern should be brought to the attention of the consumer by the industry in the form of a warning.

4. Cell Type. Vincent et al. have suggested that the newer cigarettes may be responsible for reported changes in the

prevalence of the lung cancer cell types. With the reported increase in adenocarcinoma in women, this view requires a response.

5. Additives, Flavorings, Other Ingredients. Industry emphasis on the production of lower yield cigarettes as a response to medical opinion would serve to intensify the present focus on new smoke components resulting from the addition of flavoring agents, additives or ingredients. This is a matter of considerable concern to the industry in the U.S. because it has been requested to provide information on ingredients or additives and the testing of these additives to determine their biologic activity in the smoke.

CONCLUSION

Dr. Blackman's position that the industry's current product modifications are in response to a "strong body of medical opinion" (which he describes) suffers from major scientific weaknesses. The epidemiological and histological evidence or data on which this opinion relies can be challenged on serious scientific grounds. In addition, important questions are ignored, possible alternate explanations are not discussed, and differing scientific positions are hardly mentioned. This highly selective reading of the scientific literature may be misleading and certainly gives rise to questions to which the industry has no persuasive responses.